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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,082	10/06/2003	Jacobus M. Lemmens	091856-0105	4414

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EXAMINER	
SIMMONS, CHRIS E	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
11/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/678,082	LEMMENS ET AL.	
	Examiner	Art Unit	
	CHRIS E. SIMMONS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 07/08/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Obviousness Rejection

Claims 51-59 were rejected under 35 U.S.C. 103(a) as being unpatentable over Pathak et al. (USP 6,113,944) in view of Benneker et al. (USP 5,874,447) and Chu (USP 4,675,188). **This rejection is maintained.**

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant has criticized the fact that the primary and secondary references do not teach calcium hydrogen phosphate anhydrate in form of plate shaped crystals or agglomerates or particular pH values. Applicant further asserts that the tertiary reference does not teach or suggest that its anhydrous dicalcium hydrogen phosphate product would be particularly useful for tableting sulfonate salts of paroxetine. These

arguments are not persuasive because the combination of the references provides the remedy for any alleged deficiency of any one reference individually.

Applicant asserts that the tertiary reference teaches away from the use of plate shaped crystals or (agglomerates thereof) of calcium hydrogen phosphate anhydrate as recited in the instant claims. In making this case, applicant refers to columns 1 and 2 of the tertiary reference which criticizes the anhydrous dicalcium phosphates of other prior art, such us the anhydrous dicalcium phosphates of USP 3,095,269. The '269 patent discloses a plate-like crystals of $CaHPO_4$. The tertiary reference states the $CaHPO_4$ in the references, including the '269 patent, *alone* cannot be used in dry direct compression as the particles are too fine and will not flow into the compression dies. This is not persuasive because the tertiary reference is not criticizing the plate-like crystal feature of the '269 reference. Instead it is criticizing the *size* of the crystals not the form of same. Furthermore, it is disclosed in the tertiary reference that precipitated anhydrous dicalcium phosphate, such as that disclosed in the '269 patent, is a fine, dense powder which can be *agglomerated with a binder such as starch* before it can be used in direct compression tableting (col. 1, ll. 60-3). Although the tertiary reference criticizes the $CaHPO_4$ in the '269 patent *alone,* it provides a remedy using a starch. Thus, it does not necessarily teach away from features in the reference altogether. It discloses that these features may be used when supported with other ingredients, such as a starch. Even if it does teach away from plate-like crystals, in arguendo, the tertiary reference explicitly discloses that agglomerates are a useful form for the $CaHPO_4$ in the

tertiary reference (col. 2, ll. 35-7); thus the claims reciting agglomerates alternatively with plate-like crystals are read upon by the tertiary reference.

Applicant argues that pH is not a parameter mention within any disclosure of the cited references and, therefore, it cannot be obvious to optimize pH. The examiner disagrees. The tertiary reference discloses pH parameters in making the products disclosed therein. It discloses that differences in pH can affect the shape and size of the crystals (col. 2, ll. 3-8). It discloses the pH can range from 3 to neutral when boiling. Dehydration can cause the pH to drop but it can be neutralized after anhydrous formation. It remains the position of the Office that one would have motivation to vary the pH of the composition.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. E. S./
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612